

Appln. No. 10/653,350  
Reply to Office action of June 30, 2006  
Response dated August 30, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/653,350 Confirmation No.: 3503  
Applicant. : Eun Jung Lee  
Filed : September 2, 2003  
TC/A.U. : 1647  
Examiner : Seharaseyon, Jegatheesan  
Docket No. : 027707.00017  
Customer No. : 38485  
For : GLYCOSYLATED HUMAN INTERFERON ALPHA ISOFORM

**RESPONSE**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Office action dated June 30, 2006.

**Amendments to the Claims** are reflected on page 2 of this paper.

**Remarks** begin on page 5 of this paper.

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. A recombinant human interferon alpha isoform comprising at least one N-glycosylation motif with the sequence Asn-Xaa-Ser/Thr wherein the asparagine of the motif is N-linked to acetylglucosamine and the motif is in a non-helical region of the protein.
2. A pharmaceutical composition comprising the recombinant human interferon alpha isoform according to claim 1 and a pharmaceutically acceptable carrier.
3. (Withdrawn) An isolated nucleic acid encoding the recombinant human interferon alpha isoform of claim 1.
4. (Withdrawn) The isolated nucleic acid according to claim 3, wherein the encoded recombinant human interferon alpha isoform comprises the amino acid sequence of SEQ ID NO:1 modified to contain at least one N-glycosylation motif with the sequence Asn-Xaa-Ser/Thr such that the asparagine residue of the motif occurs at a site selected from the group consisting of Cys1, Asp2, Pro4, Gln5, Thr6, His7, Ser8, Arg22, Arg23, Ile24, Ser25, Leu26, Phe27, Ser28, Cys29, Leu30, Lys31, Asp32, Arg33, His34, Asp35, Phe36, Gly37, Pro39, Gln40, Glu41, Glu42, Phe43, Gly44, Asn45, Gln46, Phe47, Gln48, Lys49, Ala50, Glu51, Thr52, Ser68, Asp77, Lys134, Tyr135, Ser136, Gln158, Glu159, Ser160, Leu161, Arg162, Ser163, Lys164, and Glu165.

5. (Withdrawn) An expression vector comprising the nucleic acid of claim 3.
6. A recombinant human interferon alpha isoform comprising the amino acid sequence of SEQ ID NO:1 modified to contain at least one N-glycosylation motif with the sequence Asn-Xaa-Ser/Thr such that the asparagine residue of the motif occurs at a site selected from the group consisting of Cys1, Asp2, Pro4, Gln5, Thr6, His7, Ser8, Arg22, Arg23, Ile24, Ser25, Leu26, Phe27, Ser28, Cys29, Leu30, Lys31, Asp32, Arg33, His34, Asp35, Phe36, Gly37, Pro39, Gln40, Glu41, Glu42, Phe43, Gly44, Asn45, Gln46, Phe47, Gln48, Lys49, Ala50, Glu51, Thr52, Ser68, Asp77, Lys134, Tyr135, Ser136, Gln158, Glu159, Ser160, Leu161, Arg162, Ser163, Lys164, and Glu165.
7. The recombinant human interferon alpha isoform according to claim 6, wherein the asparagine residue of the motif occurs at a site selected from the group consisting of Leu26, His34, and Lys134.
8. The recombinant human interferon alpha isoform according to claim 7, wherein the asparagine residue of the motif occurs at His34 and Phe36 is serine.
9. The recombinant human interferon alpha isoform according to claim 7 further comprising a second N-glycosylation motif wherein the asparagine residue of the second motif occurs at a non-redundant site selected from the group consisting of Leu26, His34, and Lys134.
10. (Withdrawn) A method for producing an N-glycosylated human interferon alpha isoform comprising:

culturing a eukaryotic host cell transformed or transfected with the expression vector of claim 8 under conditions that permit expression of the encoded recombinant human interferon alpha isoform; and

isolating the expressed recombinant human interferon alpha isoform from the culture.

**REMARKS**

This is in response to the Office Action mailed June 30, 2006 in the above-identified application. A one-month extension of time for response is requested and the required fee is enclosed.

The Examiner has issued a restriction requirement as follows:

Group 1: Claims 1-2 and 6-9 drawn to an  $\alpha$ -interferon and

Group 2: Claims 3-5 and 10 drawn to the  $\alpha$ -interferon encoding DNA, an expression vector and a method of producing the  $\alpha$ -interferon.

In response, Applicants elect to prosecute of Group I, Claim 1-2 and 6-9 in the present application, with traverse. Applicants request that Claims 3-5 and 10 be withdrawn from consideration at this time. Applicants expressly reserve the right to file the subject matter of the non-elected Claims (3-5 and 10) in a further divisional application.

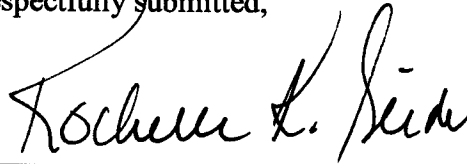
In traversing the restriction requirement, Applicants maintain that a search of all of the claims would not be a burden, since the same search terms – e.g., “interferon” and “glycosylation” would be required for both the protein and its encoding DNA. Also, there is a well-known relationship between a polypeptide and its encoding DNA, rendering these molecules part of the same patentable invention.

In view of these remarks, Applicants request that the restriction requirement be withdrawn.

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A one-month extension of time for response is respectfully requested. Payment of the extension fee is to be made by Credit Card. Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300, **referencing Docket Number 027707.00017.**

Respectfully submitted,

A handwritten signature in black ink, reading "Rochelle K. Seide". The signature is written in a cursive style with a large, looping initial "R".

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**FEE CALCULATION**

Any additional fee required has been calculated as follows:

\_\_\_\_\_ If checked, "Small Entity" status is claimed.

	(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY			LARGE ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADD'L FEE	OR	RATE	ADD'L FEE
TOTAL CLAIMS	6 MINUS	20	= 0	x \$25	\$		x \$50	\$0.00
INDEP CLAIMS	2 MINUS	3	= 0	x \$100	\$		x \$200	\$0.00
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ \$180	\$	OR	+ \$360	\$0.00
					\$			\$0.00

The U.S. Patent and Trademark Office is hereby authorized to charge and deficiency or credit any overpayment of fees associated with this communication to Deposit Account No. 01-2300 referencing docket number 027707.00017.

Under the paperwork Reduction Act of 195, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>PETITION FOR EXTENTION OF TIME UNDER 37 CFR 1.136(a)</b>		Docket Number (Optional) 027707.00017
Application Number 10/227,508	Filed September 2, 2003	
<b>GLYCOSYLATED HUMAN INTERFERON ALPHA ISOFORM</b>		
Art Unit 1647	Examiner Seharaseyon, Jegatheesan	

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.  
The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Large Entity Fee</u>	<u>Small Entity Fee</u>	
<input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ <u>120.00</u>
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ _____
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ _____

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 01-2300 (Referencing Docket No. 027707.00017). I have enclosed a duplicate copy of this sheet.

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number 32,300

☐ attorney or agent under 37 CFR 1.34  
Registration number if acting under 37 CFR 1.27 \_\_\_\_\_

*Rochelle K. Seide*  
\_\_\_\_\_  
Signature

August 30, 2006  
\_\_\_\_\_  
Date

Rochelle K. Seide, Ph.D.  
\_\_\_\_\_  
Typed or printed name

(212) 484-3945  
\_\_\_\_\_  
Telephone Number

**NOTE:** Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.36(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.